



LifeTec Group

01 _ PRECLINICAL CRO

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HEART VALVE ASSESSMENT PLATFORM



HEART VALVE ASSESSMENT PLATFORM

A versatile pulse duplicator setup for assessment of heart valves

Whether your heart valve replacement product is mechanical, of biological origin, regenerative medicine-born, or an explanted native valve, LifeTec Group's valve testing platforms can be used to accurately evaluate them.

To obtain relevant preclinical results about the performance of your heart valve replacement product, you need a physiological testing environment, which is not rigid, but can be tuned to your specific product characteristics.

LifeTec Group's heart valve testing platforms are versatile; able to assess the functioning of heart valve prostheses of different sizes and for different locations in the heart. The systems allow for accurate assessment of hydrodynamic and durability performance according to ISO guidelines.

Based on their experience with all stages of valve design and preclinical testing our expert personnel can contribute to the improvement of your product.

FEATURES & BENEFITS

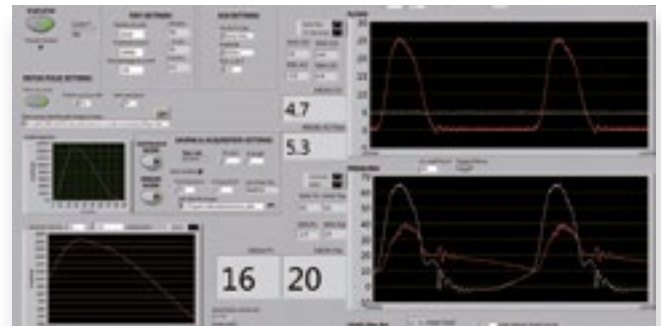


"Skilled LifeTec Group personnel operate the heart valve assessment platform"

- The LifeTec Group heart valve platform is a valuable tool to assess the quality and performance of heart valve replacement devices and tubular conduits.
- The platform is suitable for heart valve replacement products that are of mechanical design, of biological origin, regenerative medicine-born, meant for surgical implantation, and transcatheter (e.g. TAVI) procedures.

- Compatible with different working fluids (saline, blood, blood mimicking fluids).
- Assessment of the functioning of heart valve prostheses of different sizes and for different locations in the heart, aortic, pulmonary, mitral, and tricuspid.
- Full control over heart rate, stroke volume, flow rates, etc.
- Specialized and customizable valve holders available.
- Customized to your specific valve, e.g. embedding of scaffold valves.
- High-speed endoscopic video visualization of valve performance.
- Synchronized hydrodynamic performance data with high-speed video.
 - Temperature controlled.
 - Various data saving options (e.g. automated periodic data acquisition), customizable feedback controls for long term testing, and simulated ECG-output.

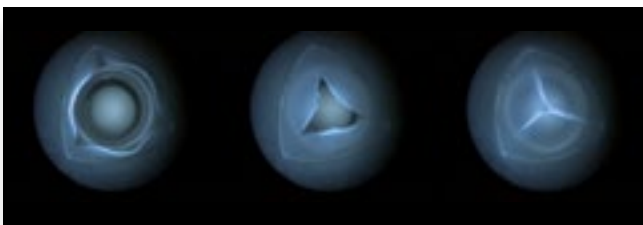
- In-house produced silicone valves are used to assure system stability.
- Accurate and validated hydrodynamic or hemodynamic performance and durability assessment, compliant with the governing regulatory guidelines (ISO5840 and ISO7198):
 - Accelerated wear testing (durability).
 - Pulsatile flow testing compliant with guideline conditions (new born, infant, toddler, child, adolescent).
 - Steady back-flow, regurgitant flow, and leakage testing.
 - Compliance testing of tubular scaffolds.
 - Burst pressure testing.
 - Effective orifice area (EOA) determination.



"Screenshot of the versatile control and readout software interface"

EXAMPLES OF USE

- Assess the performance and durability of scaffold valves with a fully controlled and tuned heart valve assessment setup.
- Assessment of the hydrodynamic performance of your valve following a successful durability test.
- Platform is adaptable to create extraordinary settings, e.g. hypertension or specific flow patterns.
- Assessment of performance of a single valve under a whole series of different hydrodynamic settings in 1 day.
- Assessment of valve performance after retrieval from an animal experiment.



"High-speed endoscopic video visualization of valve performance"



↑
"Mounted silicone reference valve"

→
"The heart valve assessment platform"



HEART VALVE ASSESSMENT PLATFORM

"Heart valve assessment platform is a platform as a service."

WHAT'S IN IT FOR YOU?



- Full regulatory guideline-compliant system, protocols, execution, and report.
- During all stages of design and preclinical assessment the skilled LifeTec Group engineers will support you. This enables you to identify deviations early on, significantly reduce the risk further down the preclinical path.
- Hydrodynamic data synchronized with visual high-speed data.
- The ability to test different sizes of valves, from different origins under various conditions.



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